

3.1 DEFINITIONS.

The following terms are defined as having the following meanings for the purposes of these policies:

- 3.1.1 OPO.** An Organ Procurement Organization (OPO) is an organization, accepted as a Member, and authorized by the Centers for Medicare and Medicaid Services (CMS) to procure organs for transplantation. For each OPO, CMS defines a geographic procurement territory within which the OPO concentrates its procurement efforts. No OPO is limited to or granted exclusive procurement rights to procure organs in its territory.
- 3.1.2 Transplant Center.** A transplant center is a hospital that is a Member in which transplants are performed. A transplant center may also be called a transplant hospital. It is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's candidate to ensure medical suitability of donor organs for transplantation into the potential recipient, including—compatibility of donor and candidate by ABO blood type. Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO with the recorded ABO of the intended recipient and UNOS Donor ID number. These actions must be documented and are subject to review upon audit.
- 3.1.3 Transplant Program.** A transplant center, or hospital, may have one or more transplant programs. Each program oversees transplantation of one or more organ types.
- 3.1.4 Waiting List.** The Waiting List is the computerized list of candidates who are waiting to be matched with specific donor organs in hopes of receiving transplants. Waiting List candidates are registered on the Waiting List by member transplant centers. The candidate's transplant program shall be responsible for ensuring the accuracy of candidate ABO data on the waiting list. Each transplant program shall implement and operate procedure for providing on-line verification of a candidate's ABO data on the waiting list against the source documents by an individual other than the person initially entering the candidate's ABO data in UNetSM. The transplant program shall maintain records documenting that such separate verification of the source documents against the entered ABO has taken place and make such documentation available for audit. Upon entry of the candidate's waitlist data, the candidate will be added to the waitlist but will not be listed as an active candidate until separate verification of the candidate's ABO data has taken place.
- 3.1.4.1** All transplant candidate interactions will be required to be completed through UNetSM by transplant programs. The Organ Center will facilitate candidate listings and modifications in the event of computer and/or Internet failure. When the Organ Center facilitates a candidate's listing or modification due to computer and/or Internet failure, the transplant center will be required to submit a statement explaining the event.
- 3.1.4.2** Each transplant candidate must be ABO typed on two separate occasions prior to listing. Two separate occasions is defined as two samples, taken at different times, sent to the same or different labs.
- 3.1.4.3** Transplant candidates shall only be listed on UNetSM with the candidate's actual blood type.

NOTE: UNetSM is the web-based electronic utility used by the OPTN contractor to conduct the business of the OPTN. UNetSM comprises the Match System, all software, applications and security architecture needed for the collection, modification, validation, reporting, management and redundancy of data associated with the tasks and activities of the OPTN.

- 3.1.5 Match System.** The Match System is the computerized algorithm used to prioritize candidates waiting for organs. It eliminates potential recipients whose size or ABO type is incompatible with that of a donor and then ranks those remaining potential recipients according to the ranking system approved by the Board.

- 3.1.6 Host OPO.** The Host OPO is the OPO which, having identified a potential organ donor, assumes responsibility for donor management and organ allocation.
- 3.1.7 Alternative Allocation/Distribution System.** The term “Alternative Allocation System” or “Alternative Distribution System” (AAD System) refers to any system, with the exception of “Variances” and “Committee-Sponsored Alternative Systems” as described in Policies 3.1.8 and 3.1.9, respectively below, used for local organ allocation or distribution, as applicable, that is different from the standard allocation or distribution system for that organ as defined by policy. Such systems are designed for the purpose of increasing organ availability and/or organ quality, reducing or addressing an inequity in organ allocation/distribution unique to the local area, and/or examining a policy variation intended to benefit the allocation/distribution system overall. They exist in the forms of (i) alternative local units (ALUs), (ii) sharing arrangements and agreements, (iii) alternative point assignment systems, and (iv) systems that may include components of more than one of these AAD Systems. Liver payback provisions currently listed within existing Alternative Allocation/Distribution Systems will be eliminated.
- 3.1.8 Variances.** The term “Variance” refers to any system for organ allocation and/or distribution that meets the criteria for a “Variance” as described in the Final Rule for operation of the Organ Procurement and Transplantation Network, 42 C.F.R. §121.8(g). Such systems may be designed pursuant to policy-making processes and the Final Rule, §121.4, as potentially temporary policies for the purpose of previewing methods for improving organ allocation or distribution. They must include a plan for data collection and analysis and have a defined time limit for the policy variation.
- 3.1.9 Committee-Sponsored Alternative System.** The term “Committee-Sponsored Alternative System” refers to an Alternative Allocation System or Alternative Distribution System developed by the relevant Committee(s) and approved by the Board of Directors to address issues in organ allocation/distribution applicable to multiple local areas but not nationally, or for which consensus to modify standard policy for the nation as a whole has not been achieved.
- 3.1.10 Local and Alternative Local Unit.** The Local Unit will be the OPO in most cases. Alternative Local Units (Alternative Local Units or ALUs) such as subdivisions of the OPO which function as distinct areas for organ procurement and distribution, entire states, Regions or other appropriate units are acceptable if they can be demonstrated to the satisfaction of the Board of Directors to fulfill the principles below and ALU application requirements, as well as adhere to applicable laws and regulations.

The principles for defining local, all of which should be addressed and appropriately balanced in each instance, are as follows:

- 3.1.10.1** There should be a single waiting list for each organ within each Local Unit. Any deviation from this principle must be submitted for approval.
- 3.1.10.2** There should be Local Unit review. The OPO or OPOs involved shall collect and review data on organ procurement, organ distribution, organ quality, and organ function for the Local Unit.
- 3.1.10.3** There should be a demonstrated inequity in organ distribution within the OPO or OPOs involved that is addressed by the ALU and corrected or at least improved within a specified period of years as shown through objective criteria. The purpose of the ALU should be to provide a system of equitable organ distribution. Equitable organ distribution should attempt to balance justice and medical utility.
- 3.1.10.4** There should be monitorable organ distribution. Data collection and review are necessary to be certain that the distribution system is being followed and that it is achieving its goals.
- 3.1.10.5** There should be no organ distribution predicated on the procuring transplant center or individual.

3.1.10.6 There should be effective organ procurement throughout the Local Unit. Enhancement of the organ supply should be a primary goal of any organ distribution system.

In cases where a subdivision of an OPO is the Local Unit, organs recovered, but not used within that segment of the OPO will be used in the remainder of the OPO before regional or national distribution. Cooperative working relationships within and among OPOs are encouraged to serve the best interests of transplant candidates, in a manner that is consistent with the principles set forth in the Policy 3.1.10.

Once an ALU is approved, Members participating in the ALU are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.6.

3.1.11 Sharing Arrangement and Sharing Agreement. The term sharing arrangement refers to an arrangement entered into by two or more OPOs to share organs, interregionally or intraregionally, between or among the OPOs. OPOs may distribute organs pursuant to a sharing arrangement after fulfilling the Sharing Arrangement/Sharing Agreement application requirements and obtaining approval by the Board of Directors. Organs must be distributed within the sharing area on the basis of a common Waiting List unless an appropriate Alternative Local Unit for the area is approved by the Board of Directors. Unless specifically required for examining the effectiveness of the Sharing Agreement, as required by its evaluation plan, OPOs participating in a sharing arrangement must have geographically contiguous service areas. The term sharing agreement refers to the written document that defines the sharing arrangement.

Once a Sharing Arrangement is approved, Members participating in the Sharing Arrangement are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.6.

3.1.12 Alternative Point Assignment Systems. An OPO, Members participating in an approved Alternative Local Unit or Members participating in an approved sharing arrangement may assign to each of the point system criteria set forth in Policies 3.5 through 3.11 a number of points other than the number of points set forth in such policies for allocation of local organs after fulfilling the alternative point assignment system application requirements and obtaining approval by the Board of Directors. Members participating in an approved alternative point assignment system shall be obligated to: (a) stay aware of all applicable provisions of the organ allocation policies and any amendments thereto ("policy requirements") (as well as all other Bylaws and Policies), (b) evaluate the continued benefit of the system in light of the policy requirements and (c) request Committee and Board of Director approval for any adjustment to the alternative point assignment system deemed appropriate and desirable by the Member(s) following such evaluation. No approved alternative point assignment system will automatically be modified in light of or to incorporate in any way any policy requirement adopted by the Board of Directors following approval of the system unless otherwise specifically provided by the Board of Directors. Any modification of an approved alternative point assignment system shall require application by the applicable Member(s) in accordance with Policy 3.4.6.4.

Once an alternative point assignment protocol is approved, Members participating in the protocol are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.6.

3.1.13 Definition of Directed Donation – OPOs are permitted to allocate an organ(s) to a specific transplant candidate named by the person(s) who authorized the donation unless prohibited by state law. All recipients of a deceased donor organ(s) from a directed donation must be added to the waiting list prior to transplantation.

When the candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant center must document the reason why the candidate does not appear and ensure that the organ is safe and appropriate for the

candidate. The transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting the candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
 - ABO;
 - Serologies;
 - Donor HLA and candidate's unacceptable antigens;
 - Height; and
 - Weight.